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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madame,

I am writing to provide my comments for the document, **Docket Number: 03D-0060, Guidance for Industry Part 11, Electronic Records; Electronic Signatures-Scope and Application-Draft Guidance.**

For many years I have worked in regulated industry, including responsibilities in large scientific systems development and support. For the past fifteen years I have been an industry consultant focusing on computer system validation, and have worked with many regulated companies. I have supported the FDA requirements for computer systems, including Part 11 requirements, because the FDA consistently focused on quality standards for the development and support of computer systems. My experience in compiling computer related citations of noncompliance over the last eleven years also has reinforced my view that FDA inspectors focus on appropriate quality measures.

The largest part of this letter contains detailed comments for the guidance document. My overall impression of the document, I'm very sorry to have to say, is not positive. I believe the document can too easily be interpreted to mean that FDA inspectors will take a hiatus from inspecting computer systems during the re-examination of Part 11. This is the first time I have reviewed an FDA document that raises many questions, and does not clearly focus on ensuring quality. The inconsistencies in the document have, from my perspective, created a mixture of confusion and relief in industry. There are those who have decided that this guidance has more weight than regulations, and have cut all Part 11 related budgetary dollars and dropped Part 11 related projects. Thankfully, there are others who have maintained their interest in building and operating computer systems following quality standards.

I am very concerned to have not found any influence in this guidance from FDA inspectors. Validation, audit trails, record retention, and record copying are all critical requirements in the predicate rules, and are reviewed routinely by inspectors. This document continually presents two conflicting statements in a row, with regard to these four topics. Saying that the FDA will use enforcement discretion, and then saying you

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have to meet the predicate rules for these four issues, is so inconsistent to readers that many have taken these statements to mean they cover the spectrum of possibilities—from ignoring the requirements, to maintaining full compliance with them. This may result in the belief by industry that an infinite number of compliance levels are appropriate. Since FDA guidance has previously provided clear minimum standards, in my view, this document does not provide a positive situation. I am imploring FDA to consider this, and my more detailed comments.

I thank you for the opportunity to offer my comments and concerns. My detailed comments are as follows:

Introduction

Lines 31-33

It would be beneficial to state that since Part 11 was released five and a half years ago, a re-examination of these regulations is appropriate at this point in time, regardless of the cGMP initiative.

Lines 35-38

From what I have seen so far, these bold statements have set the tone for this guidance and caused many to drop Part 11 compliance efforts. Please reconsider these statements. The current tone of the document appears to be incongruous with FDA's previous work to ensure quality practices.

Lines 36-39

These two sentences are in direct conflict with each other. Validation, audit trails, record retention, and record copying have been significant predicate rule requirements for computer systems for at least fifteen years. How could the FDA avoid taking regulatory action on noncompliance with these requirements without sending a message to industry that predicate rules are no longer of value?

Lines 41-44

When Part 11 was released the FDA clarified, and since then has reinforced, that any system retired from use as of August 20, 1997 was NOT subject to Part 11. Is this what is meant here by a legacy system? This terminology needs to be clarified.

Lines 46-50

I would move these sentences in front of line 31. Perhaps this could help minimize some of the wild interpretations of this guidance.

Background

Line 81

It would be best to delete this sentence. It can too easily be interpreted as evidence of political in-fighting or personality conflicts within the FDA.

Lines 82-88

Frankly, since Part 11 was released in it's final form, I have not seen even one of these three issues as a legitimate concern. Some in industry have at times been interested in purchasing products that do not meet requirements like having an automated audit trail or basic security controls. These are legitimate requirements for ensuring data integrity. Many vendors' products are sold to a wide variety of industries, and the vendors are not aware of regulatory concerns and have no interest in developing features that ensure data integrity. (In industries where mistakes have no impact on public health or safety, data integrity may not be a concern.) Avoiding such products is not my idea of either discouraging innovation or restricting the use of technology.

The cost of implementing Part 11 has been grossly overstated in many cases. The validation efforts that were required throughout the 1990s, and never got done, more often than not got lumped into Part 11 compliance cost estimates. Before Part 11, risk assessments may have determined that computer system validation was not necessary. Part 11 made it clear to industry that computer system validation was a legitimate regulatory requirement. This guidance document now questions that requirement.

Discussion—A. Overall Approach to Part 11 Requirements

Lines 118-124

Again, the last two bullets in this list are in conflict with each other. See the comments for Lines 36-39 above.

Lines 125-135

Thank you for reinforcing the remaining Part 11 requirements. I am still very puzzled as to why the FDA has singled out validation, audit trails, record retention and record copying, especially since these are such critical requirements. Since FDA has opened the door with these four requirements, I would not be surprised if the push now will be for "enforcement discretion" for all of Part 11.

Discussion—B. Details of Approach-Scope of Part 11

Lines 151-154

The incidental use of a computer system needs clarification. The "Typewriter Excuse" that has been known by industry for many years has the following requirements: data/information must be captured originally on paper; once the data/information is transcribed into a computer, each printout of the data/information must be 100% proofed to ensure data integrity; all manipulation of the data (i.e., search and sort) must be done by hand; all storage and retrieval of the data for regulatory purposes is done through a paper filing capability. If these requirements are met, the computer system is truly used as a typewriter, and is thus incidental to the generation of the regulated information/data. These types of computer systems have not been subject to Part 11 since August 20, 1997. Similar detailed rules for incidental use of computers are needed in this document.

Lines 163-192

I find these definitions confusing. Please see the detailed comments below. The simplest definition I have seen for records that fall under the jurisdiction of the regulations is as

follows: records that are specifically required by predicate rules, or any records that are used to help make regulatory related decisions.

Lines 164-167
Delete this second sentence. The first sentence adequately and clearly states the intent, which is also the intent that has been stated by FDA since August 20, 1997.

Lines 168-170
This sentence can be deleted. I think it raises more questions than it answers. If this sentence remains in the document, please add an explanation of what "relied on to perform regulated activities" means. Do you mean activities such as sorting, analyzing, or manipulating regulatory data? Do you mean storing the electronic information for future access? Do you mean using the electronic data to make regulatory related decisions? If you keep this sentence please clarify.

Lines 171-178
If you define "relied on to perform regulated activities", I think these lines can be deleted.

Lines 184-187
It makes sense to ensure that any information submitted to the FDA in electronic form comes from a system that is Part 11 compliant.

Lines 187-190
I am hard pressed to think of records that are used in generating a submission, that are not required to be maintained, since the records have all been used to make regulatory related decisions. Please give examples of records that would not be considered Part 11 records in this case.

Lines 191-192
There are many who may take issue with this sentence because it also includes initials and general signings. I agree that they should be covered by the electronic signature requirements contained in Part 11.

Discussion—C. Approach to Specific Part 11 Requirements
Lines 198-201
These two sentences are in direct conflict with each other. Validation of computer systems has long been a requirement based on the predicate rules. By making these inconsistent statements the options for interpretation become infinite. There are those who now believe that FDA inspectors will not issue citations of noncompliance related to Part 11 and computer systems. This would indicate that regulations that have been in place for many years have no significance.

Lines 203-205
This sentence implies that industry does not necessarily need to validate computer systems that contain Part 11 related records. This makes no sense to me. How can a company prove that their records are accurate and complete without validating the system

that contained/manipulated those records? It is important to remember that the major product given to FDA by industry is information. The best tool we have for handling information (i.e.,searching, sorting, analyzing, storing) is the computer; so it makes sense to ensure validation of computer systems.

Lines 205-210
If the decision is supposed to be based on predicate rules, then validation is a definite requirement, and has been for several years. Risk assessment is being done and has been done for many years in industry. Again, these sentences serve primarily to give the impression that an infinite number of interpretations of compliance are possible.

Lines 212-214
Good references. I would like to see the tone and content of this guidance be more consistent with these references.

Lines 224-227
I don't understand the wording of this sentence. It is definitely important to have audit trails and security controls to ensure the reliability of records. Under what circumstances is it not important to ensure the reliability of records? It is my understanding that the requirement of automated audit trails in Part 11 is a critical requirement to ensure the long term integrity of electronic records. With paper records there are forensic means for determining fraudulent activities like erasures or modifications. In the electronic environment, I can think of no other obvious means than an automated audit trail, to determine if a record or value has been changed. Electronic records could be sitting on a computer system for years. What other mechanism can ensure records on a computer system have not been tampered with during normal operations? These lines again have opened the door for an infinite number of interpretations.

Lines 236-240
Please define clearly what a legacy system is. These sentences are again subject to an infinite number of interpretations.

Lines 244-261
These statements are consistent with FDA's interpretation of Part 11 since August 20, 1997. I don't see how this shows "enforcement discretion", as it just restates the original intent.

Lines 265-273
These first two statements are in direct conflict with each other. The predicate rules clearly require long term retention, and the ability to reconstruct the original regulatory data/information. The inspectors have always used discretion in determining what is possible for long term retention of electronic records. Of course there are issues with maintaining electronic records over time, but FDA has typically looked for a reasonable approach and good faith effort. Citations I have seen related to this area (there are few) have typically been a result of blatant noncompliance.

Lines 275-279

These two statements are in direct conflict with each other. The predicate rules have for many years required the ability to reconstruct the original regulatory data/information. Reconstruction may not be possible if the original electronic media is not maintained. In most cases, the original electronic media can be maintained and still be accessible for several years. It makes sense to maintain the original electronic media while it has reconstruction value. I can see companies immediately putting their data into pdf format and forgetting about the original media. This could put companies in great jeopardy if a question of fraud or data integrity comes up when the FDA is reviewing a submission, or if re-analyses are necessary because something was done incorrectly. The companies could then blame FDA for making it impossible or extremely difficult and time consuming to respond. Guiding industry to do this is, in my view, asking for trouble in the future.

Lines 279-280

This sentence re-emphasizes the interpretation made by the FDA since August 20, 1997, for a hybrid system. The FDA also has emphasized that it makes sense to have a vision of moving towards electronic signatures sometime in the future. This makes sense, as handwritten signatures executed to a paper printout captures the data and the approval at that moment in time, but could easily be replaced with another printout and handwritten signature 2 hours later, with no one being any the wiser. This situation can be greatly alleviated with electronic signatures and the appropriate Part 11 controls. I think this vision of working towards an electronic future should also be captured in this document.

Again I thank you for considering my comments and concerns.

Very truly yours,

Karen Raskasky

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